

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hatcher et al. )  
Serial No.: 10/616,884 ) Group Art Unit: 1618  
Filed: July 10, 2003 )  
For: SOL-GEL DERIVED BIOACTIVE GLASS )  
POLYMER COMPOSITE )

## **PRE-APPEAL BRIEF REQUEST FOR REVIEW**

**Mail Stop AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In response to the Office Action dated 09-25-2009, and in conjunction with the Notice of Appeal filed concurrently herewith, the Applicants submit the following remarks in support of the Pre-Appeal Brief Request for Review:

## **REMARKS**

### **Claims Rejected under 35 U.S.C. § 102**

Claims 11, 13, 21- 25, 28, 30, 34, 36, 37, 39, 41 42 and 44 are rejected under 35 U.S.C. §102 (a) as being anticipated by U.S. Patent No. 6,328,990 to Ducheyne et al. (hereinafter “Ducheyne”). (Office Action dated 09-25-2009, page 2)

Claims 11 – 17, 28 – 32, 34, 35, 38 and 41 – 42 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,721,049 to Marcolongo et al. (hereinafter “Marcolongo”) (Office Action dated 09-25-2009, page 3)

### **Claims Rejected under 35 U.S.C. § 103**

Claims 11, 13, 21 – 29, 34 – 39, 41, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 6,328,990 to Ducheyne in view of U.S. Patent No. 5,591,453 to Ducheyne (hereinafter Ducheyne ‘453). (See Office Action dated 09-25-2009, page 5)

Claims 11, 12, 14, 18 – 20, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ducheyne in view of U. S. Patent No. 5,711,960 to Shikinami (hereinafter Shikinami). (Office Action 09-25-2009, page 7)

With regard to the two anticipation rejections and the two obviousness rejections listed above, the main issue that the Applicants seek a resolution (from the pre-appeal conference) from is the Examiner’s contention that the use of the word “reacted” is a product-by-process limitation. The Applicants believe that the term “reacted” is a structural limitation and not a product-by process limitation as contended by the Examiner.

In making the rejection under 35 U.S.C. 102 over Marcolongo, the Examiner states that “Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. In the instant case the instant claims are defined by a

composite comprising a biocompatible polymer and a bioactive glass.” (Office Action dated 09-25-2009, page 3) This is inaccurate.

In addition, with regard to the rejection under 35 U.S.C. 103(a) over Ducheyne in view of Shikanami, the Examiner has stated that “[O]nce the Examiner provides rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the Applicant to come forward with evidence produced by a different process, the burden shifts to the Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.” (See Office Action dated 09-25-2009, page 8)

In the first instance the Examiner has produced no rationale for why the Applicants claim is a product by process limitation and not a structural limitation. The Applicants contend that the term “reacted” is a structural limitation and not a product-by-process limitation. The Applicants believe that the term “reacted” indicates that the polymer is reacted with the glass. The examples of the Applicants invention clearly explain to one of ordinary skill in the art that the precursors to the bioactive glass involve reactive metal alkoxides that undergo reactions to form the bioactive glass. If these precursors did not undergo a reaction with the bioactive polymer or with themselves, there would be no glass that could be claimed in the present invention. Neither Marcolongo, Ducheyne, Ducheyne ‘453 nor Shikanami use these metal alkoxides or any other species that undergo a reaction with polymers. Marcolongo, Ducheyne, and Shikanami teach metal oxides that are not capable of reacting with the polymers. Ducheyne ‘453 teaches metal alkoxides, but does not teach that its products contains any polymers. In short, Marcolongo, Ducheyne, Ducheyne ‘453 and Shikanami do not teach all elements of the claimed invention either individually or in combination. Thus Marcolongo, Ducheyne, Ducheyne ‘453 or Shikanami cannot be used in an anticipation rejection or an obviousness rejection against the claimed invention.

The Applicants submit that the Examiner has provided no basis for why the term “reacted” is a product by process limitation. If however, the term “reacted” is a product-by-process limitation, then every verb used in a claim, such as for example, “disposed”, “formed”, “twisted” and the like, must, by analogy be a product-by-process limitation.

This is patently absurd. If every structural limitation in a claim that involved the use of a “verb” was misconstrued as a product-by-process limitation, very few claims directed to the “statutory class of articles or compositions” would ever be allowed.

The Applicants believe that the Examiner is wrong. The courts have adjudicated numerous disputes pertaining to the use of terms such as “reacted” in claims. The courts have consistently held that a term that “can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and **by default interpreted in their structural sense**, unless the patentee has demonstrated otherwise.” *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371-72 (Fed. Cir. 2003). For example, the CCPA held that

[T]he recitation of the particles as ‘interbonded one to another by interfusion between the surfaces of the perlite particles’ is as capable of being construed as **a structural limitation** as ‘intermixed,’ ‘ground in place,’ ‘press fitted,’ ‘etched,’ and ‘welded,’ all of which at one time or another have been separately held capable of construction as structural, rather than process, limitations. (*emphasis added*)

*In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969); *see also AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1372-73 (Fed. Cir. 2004) (holding that the term ‘multiple depositions’ does not refer to a process but is only relevant if multiple depositions “affect the **structure** and optical properties” of the claimed material”); *Vanguard Prods. Co. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (holding that the claim term “integral” describes a **structural relation**, not the particular manufacturing process related in the specification); *Hazani v. United States Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (“the ‘chemically engraved’ limitation, read in context, describes the product more by its **structure** than by the process used to obtain it.”).

In summary, since neither Ducheyne nor Marcolongo teach that the bioactive glass reacts with the bioactive polymer, they cannot anticipate the claimed invention. In addition, since neither Ducheyne ‘453 nor Shikanami teach that the bioactive glass reacts with the bioactive polymer, they too cannot anticipate the claimed invention. Since neither Ducheyne in view of Ducheyne ‘453 nor Ducheyne in view of Shikanami teach all elements of the claimed invention, the Applicants believe that the Examiner has not

made a prima facie case of obviousness over Ducheyne in view of Ducheyne '453 or Ducheyne in view of Shikanami.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Assignee.

Respectfully submitted,

CANTOR COLBURN LLP  
Applicants' Attorneys

By: /David E. Rodrigues/  
David E. Rodrigues  
Registration No. 50,604

Date: January 25, 2010  
Cantor Colburn LLP  
20 Church Street, 22<sup>nd</sup> Floor  
Hartford, CT 06103  
Customer No.: 23413  
Telephone: (860) 286-2929